

Notice of Allowability

Application No.

10/799,005

Examiner

Michael Szperka

Applicant(s)

RASMUSSEN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4 October 2005.
2. ☒ The allowed claim(s) is/are 1-10, 12 and 13.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>12/14/05</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>10/31/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Proposed Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Ignacio Perez de la Cruz on December 14, 2005.

Applicant's Information disclosure statement received October 31, 2005 is acknowledged and has been considered.

In the Claims:

In claim 1, delete line 2 and replace with -- of SEQ ID NO:1 or a pharmaceutically acceptable salt thereof.--

Delete claim 3 and replace with -- A composition comprising the pharmaceutically acceptable salt of the polypeptide of claim 1 and a pharmaceutically acceptable carrier.--

Cancel claim 11.

Delete claim 12 and replace with --An isolated polypeptide wherein the polypeptide has an acetyl cap at its N-terminus, an amide cap at its C-terminus, or both, and consists of the amino acid sequence of SEQ ID NO:1.--

Delete claim 13 and replace with --A composition comprising the polypeptide of claim 12 and a pharmaceutically acceptable carrier.--

2. The following is an examiner's statement of reasons for allowance:

The rejection of the claimed invention under 35 USC 112, first paragraph for lack of enablement has been withdrawn because the claimed peptide is essentially equivalent to a peptide disclosed by Veldman that can reasonably be used in methods of diagnosing pemphigus vulgaris (PV). This is because Veldman III (J. Immunol. 2003, 170:635-642, newly cited by the examiner, see entire document) teaches that DG3-reactive T cells can be found in healthy controls and in PV patients, but that T cells of the Th2 phenotype are only found in PV patients (see particularly the abstract, the last sentence of the introduction, and Figure 1). Examination of the data presented in Tables I and II of Veldman indicate that T cells recognizing the peptide that is essentially equivalent to SEQ ID NO:1 (identified as DG3(189-205) in Tables 1 and 2) are only of the Th1 subset in cells from healthy individuals (see Table 2) and are only of

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the Th2 subset in PV patients (see Table 1). As such it appears that identification of Th2 cells reactive with a peptide corresponding to SEQ ID NO:1 is a clear diagnostic marker for the disease PV. As indicated above, the art peptide is not identical to the claimed peptide. SEQ ID NO:1 differs from the peptide of Veldman by the addition of 3 residues to the N-terminus and the deletion of one amino acid from the C-terminus. The specification discloses that the peptide of SEQ ID NO:1 binds to MHC class II molecules and teaches that the peptide binding groove of Class II molecules is open such that peptides of differing length can be accommodated, with the amino acids that make contact with T cell receptors being located in the middle of the peptide (see particularly from the middle of page 47 to page 51). The middle of the peptide is precisely the region that is identical between the peptide of Veldman and SEQ ID NO:1, and as such its recognition by the immune system would be equivalent and therefore the instant claimed peptide could also be used in methods of diagnosis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
December 14, 2005


CHRISTINA CHAN
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